Wolters Kluwer
When you have to be right

Chapter 5
Ethics in Research

Historical Background

- 1930s and 1940s: Nazi medical experiments
  - Subjects exposed to harm and forced to participate
- 1932–1972: Tuskegee Syphilis Study
  - Withheld medical treatment
- 1940s: U.S. radiation experiments

Codes of Ethics

- 1949: Nuremberg Code: response to Nazi atrocities
- 1964: Declaration of Helsinki: World Medical Assn.
- 1978: Belmont Report
- 1995: ANA Ethical Guidelines in the Conduct, Dissemination, and Implementation of Nursing Research
- 2002: CNA: Ethical Research Guidelines for RNs
- 2015: ANA declares Year of Ethics: Revised Code of Ethics for Nurses with Interpretive Statements

Ethical Dilemmas in Conducting Research

- **Ethical dilemma** in research: a situation in which the rights of study participants are in direct conflict with requirements of a study
- Examples of dilemmas
  - Does a new medication prolong life in patients with AIDS?
  - Are nurses equally empathic in their treatment of male and female patients in the ICU?

Ethical Principles: The *Belmont Report*

- Beneficence
  - Imposes a duty on researchers to minimize harm and maximize benefits
- Respect for human dignity
  - Includes the right to self-determination and the right to full disclosure
- Justice
  - Includes participants' right to fair treatment and their right to privacy

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Beneficence

- Principle of beneficence: Above all, do no harm.
- **Right to freedom from harm and discomfort**
  - **Beneficence**—minimize harm; maximize benefits
- **Right to protection from exploitation**
  - Participants should not be placed at a disadvantage.
  - This special relationship should not be exploited.

Question

Tell whether the following statement is True or False.

The Nuremberg Code was one of the first established sets of ethical standards.

a. True

b. False

Answer

a. True

Rationale: One of the first international efforts to establish ethical standards was the Nuremberg Code. These ethical standards were developed in 1949 in response to the Nazi atrocities.

Principle of Respect for Human Dignity

- Right to **self-determination** (absence of coercion)
  - Deciding voluntarily whether to participate in a study, without risking prejudicial treatment
  - Having the right to ask questions, refuse answering questions, and drop out of the study
- Right to **full disclosure** (absence of deception or concealment)
  - Receiving a description of the study, the person's right to refuse participation, and potential risks and benefits

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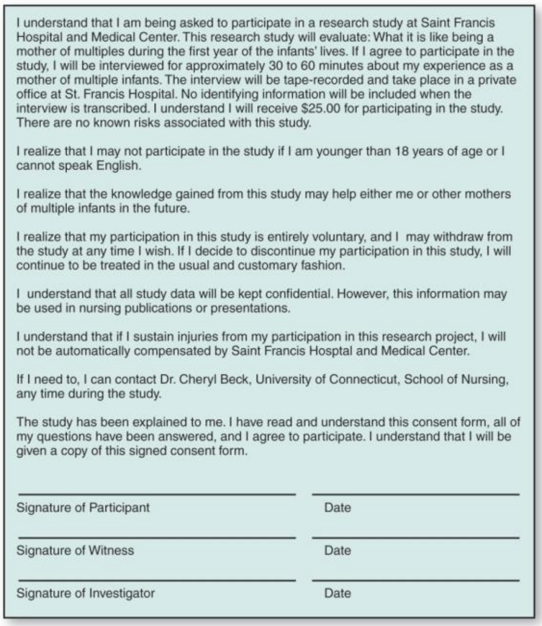
Principle of Justice

- **Right to fair treatment**
  - Concerns the equitable distribution of benefits and burdens of research
- **Right to privacy** (confidentiality, anonymity)
  - Ensures that the research is not more intrusive than it needs to be and that privacy is maintained

Procedures for Protecting Study Participants

- Risk–benefit assessments
- Informed consent
- Confidentiality procedures
- Debriefings and referrals
- Treatment of vulnerable groups
- External reviews and the protection of human rights
- Ethical issues in using animals in research

Potential Benefits and Risks to Study Participants



I understand that I am being asked to participate in a research study at Saint Francis Hospital and Medical Center. This research study will evaluate: What it is like being a mother of multiples during the first year of the infants' lives. If I agree to participate in the study, I will be interviewed for approximately 30 to 60 minutes about my experience as a mother of multiple infants. The interview will be tape-recorded and take place in a private office at St. Francis Hospital. No identifying information will be included when the interview is transcribed. I understand I will receive $25.00 for participating in the study. There are no known risks associated with this study.

I realize that I may not participate in the study if I am younger than 18 years of age or I cannot speak English.

I realize that the knowledge gained from this study may help either me or other mothers of multiple infants in the future.

I realize that my participation in this study is entirely voluntary, and I may withdraw from the study at any time I wish. If I decide to discontinue my participation in this study, I will continue to be treated in the usual and customary fashion.

I understand that all study data will be kept confidential. However, this information may be used in nursing publications or presentations.

I understand that if I sustain injuries from my participation in this research project, I will not be automatically compensated by Saint Francis Hosptal and Medical Center.

If I need to, I can contact Dr. Cheryl Beck, University of Connecticut, School of Nursing, any time during the study.

The study has been explained to me. I have read and understand this consent form, all of my questions have been answered, and I agree to participate. I understand that I will be given a copy of this signed consent form.

Signature of Participant Date

Signature of Witness Date

Signature of Investigator Date

Question

The principle of justice ensures a research subject's right to:

a. Self-determination

b. Full disclosure

c. Protection from harm

d. Privacy

Answer

d. Privacy

Rationale: The principle of justice ensures a research subject's right to privacy and fair treatment. The right to self-determination and the right to full disclosure are ensured by the principle of respect for human dignity. The right to protection from harm is ensured by the principle of beneficence.

Informed Consent

- Participants have adequate information about the research.
- Participants can comprehend that information.
- Participants have free choice in deciding whether to participate in or withdraw from the study.
- Researchers usually document informed consent by having participants sign a consent form.

Consent Form

- **Informed consent** means that participants have adequate information about the study, comprehend the information, and have the power of free choice, enabling them to consent to or decline participation voluntarily.
  - **Implied consent** (e.g., for self-administered questionnaires)
  - **Process consent** (renegotiated over time, qualitative studies)

Confidentiality Procedures

- **Anonymity**—researchers cannot link participants to their data.
- **Confidentiality in the absence of anonymity**—other confidentiality procedures need to be implemented.
  - Taking steps to ensure breach of confidentiality does not occur
- **Certificate of Confidentiality (NIH)**—a certificate obtained to prevent forced disclosure of confidential information to authorities

Debriefings and Referrals

- It is sometimes advisable to offer **debriefing** sessions following data collection so that participants can ask questions or share concerns.
- Researchers can also demonstrate their interest in participants by offering to share study findings with them after the data have been analyzed.
- Finally, researchers may need to assist participants by making referrals to appropriate health, social, or psychological services.

Treatment of Vulnerable Groups

- **Vulnerable subjects** are study participants who require special protections.
  - May be incapable of giving fully informed consent (e.g., cognitively impaired people) or may be at high risk for unintended side effects (e.g., pregnant women)
  - Some (e.g., children) cannot make a truly informed decision about voluntary participation.

Groups Considered Vulnerable

- Children
- Mentally or emotionally disabled people
- Severely ill or physically disabled people
- Terminally ill people
- Institutionalized people
- Pregnant women

External Review and Protection of Human Rights

- Ethical aspects of a study are increasingly likely to be reviewed before permission is granted to conduct a study.
  - Human subjects committees
  - **Institutional Review Boards (IRBs)**
  - Research Ethics Boards (REBs—in Canada)

Question

Tell whether the following statement is True or False.

Children require special protection when they are involved in a research study.

a. True

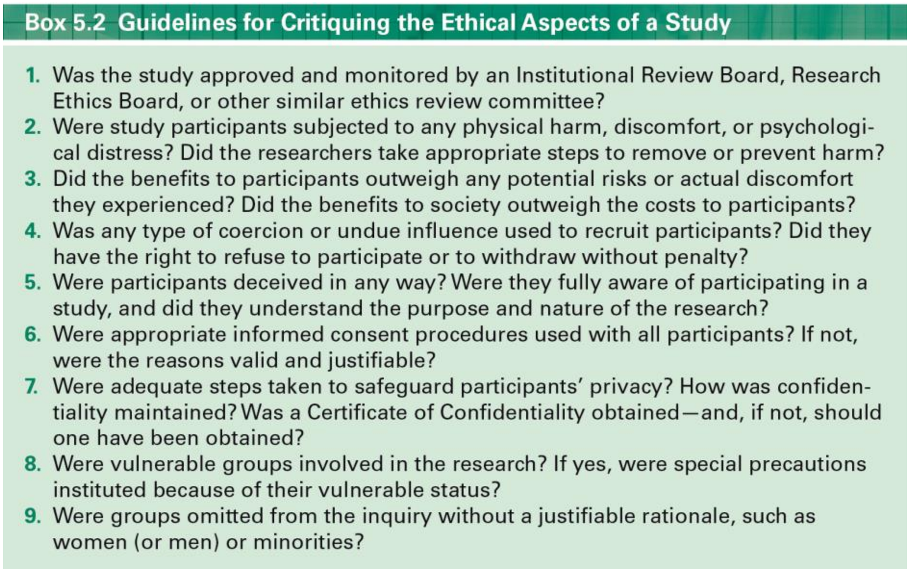
b. False

Answer

a. True

Rationale: Children, because of their inability to make a truly informed decision about voluntary participation in a research study, are considered vulnerable and thus require special protection.

Guidelines for Critiquing the Ethical Aspects of a Study



Box 5.2 Guidelines for Critiquing the Ethical Aspects of a Study

1. Was the study approved and monitored by an Institutional Review Board, Research Ethics Board, or other similar ethics review committee?
2. Were study participants subjected to any physical harm, discomfort, or psychological distress? Did the researchers take appropriate steps to remove or prevent harm?
3. Did the benefits to participants outweigh any potential risks or actual discomfort they experienced? Did the benefits to society outweigh the costs to participants?
4. Was any type of coercion or undue influence used to recruit participants? Did they have the right to refuse to participate or to withdraw without penalty?
5. Were participants deceived in any way? Were they fully aware of participating in a study, and did they understand the purpose and nature of the research?
6. Were appropriate informed consent procedures used with all participants? If not, were the reasons valid and justifiable?
7. Were adequate steps taken to safeguard participants' privacy? How was confidentiality maintained? Was a Certificate of Confidentiality obtained—and, if not, should one have been obtained?
8. Were vulnerable groups involved in the research? If yes, were special precautions instituted because of their vulnerable status?
9. Were groups omitted from the inquiry without a justifiable rationale, such as women (or men) or minorities?